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Summary of Safety and Effectiveness Information	AESCULAP® INC.
Premarket Notification, Section 510(k)	DECEMBER 5, 2000

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name:
Trade Name: **macs**^{TL} modular anterior construct system

Common Name(s): Anterior thoraco-lumbar spine plates

Classification Name(s): Spinal intervertebral body fixation orthosis

Establishment Name & Registration Number:

Name: Aesculap® Inc.
Number: 2916714

Classification(s):

§ 888.3060 Spinal intervertebral body fixation orthosis.

Identification. A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct sway back, scoliosis (lateral curvature of the spine), or other conditions.

Classification. Class II.

Device Class: Class II for all requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): KWQ

Applicant Name & Address:
Aesculap® Inc.
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South San Francisco, CA 94080-7028
650.876.7000 voice - 650.876.0266 fax

Company Contact:
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Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Performance Standards (Section 514 compliance):
Food and Drug Administration mandated Performance standards for anterior spine plates are not in effect. AESCULAP® INC. intends to comply with all voluntary Performance Standards applicable to the **macs**^{TL} modular anterior construct system. At the present time, various performance standards such as ASTM, ISO, QSR/CGMP and in-house SOP standards are used. In addition, AESCULAP® INC. complies with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

Special Controls:
All Class II devices are subject to Special Controls. No FDA mandated special controls are in effect at the present time.

Labeling:
The **macs**^{TL} modular anterior construct system discussed in this premarket notification will be manufactured for AESCULAP® INC. and labeled as such. The system will be marketed exclusively to healthcare facilities and physicians.

Surgical Technique. The surgical approach of the **macs**^{TL} modular anterior construct system is similar to other anterior thoraco-lumbar plate spinal systems.

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician only.

Warning: This device is not approved for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material in building a construct. Components of the **macs**^{TL} modular anterior construct system should NOT be used with components from any other system or manufacturer.

"**Precaution:** The implantation of the **macs**^{TL} modular anterior construct system should be performed only by experienced spinal surgeons with specific training in the use of such spinal devices because the technique is a technically demanding procedure presenting a risk of serious injury to the patient."

Preamendments Device (legally marketed comparison device):
AESCULAP® Inc. believes that the **macs**^{TL} modular anterior construct system is substantially equivalent to the following spinal device system marketed by Theken Surgical.

BodyForm® - Thoraco-Lumbar Fixation System, K983622 - Theken Surgical, LLC.

Centaur™ Spinal System - K994347 - Howmedica/Osteonics/Stryker

The **BodyForm® - Thoraco-Lumbar Fixation System** is cleared for marketing. **BodyForm®** is a spinal construct made up of one plate contoured to match the lateral profile of the thoraco-lumbar vertebral bodies, four Morse taper headed screws, and two locking set screws. The plates are sized and designed in such a way that they will accommodate particular bone graft heights. The **BodyForm®** is intended to be used for the surgical treatment of spinal instability or deformity. Equivalence can be seen in the design, material composition, surgical technique, testing methodologies and intended use.

The **Centaur™ Spinal System** is cleared for marketing. Used anteriorly, the **Centaur™ System** is a spinal construct manufactured from ASTM F-136-96 titanium alloy (Ti6Al4V). The system is comprised of primary and secondary bone screws, rods, lateral connectors, plates and accessories. The **Centaur™ Spinal System** is intended to treat deformities of curvature, fracture, tumor, spinal stenosis, spondylosisthesis, failed previous spine surgery and degenerative disk disease. Equivalence can be seen in the design, material composition, surgical technique, testing methodologies and intended use.

To facilitate comparison of the **macs**^{TL} modular anterior construct system to the systems identified above, a basic feature comparison table is located at the end of the document.

Summary of Biomechanical Testing:
In the compression-bending test the results are satisfactory.
In the torsion test the ultimate torque of the plate and rods is satisfactory.
The fatigue endurance of the rod and plate constructs is satisfactory.
Axial slippage resistance of the plate and the pairs of rods are satisfactory.

Results and Conclusions:
The stiffness of the plate system is equivalent to that of the rod system.
The fatigue performance is comparable and within the required specifications.
These results show that the performance of the **macs**^{TL} system is comparable to other systems on the market when the published data are reviewed.

Summary Basis for Equivalence and Comparison Table:
Biomechanical studies conducted on the **macs**^{TL} modular anterior construct system implant constructs demonstrate that the device system is safe, effective, and suitable for use as a spinal fixation device system. Based on the available information concerning the referenced comparison devices, these devices are similar in that:

- The devices have the same intended use and indications for use.
- The devices are made of the same implant alloy.
- The devices have similar form, function, components, instruments, dimensions, geometry and features.

The use of QSR based process controls, testing standards (ASTM F-1717 - 96 testing, materials standards (ASTM F-136, 92 and ISO 5832-3) and the similarities of the references comparison devices establish that the **macs**^{TL} modular anterior construct system is substantially equivalent to available legally marketed anterior thoraco-lumbar spinal devices. It is believed that the anticipated clinical performance of the **macs**^{TL} modular anterior construct system is equivalent to the referenced systems.

Summary Comparison Table:

FEATURE	**macs**^{TL} modular anterior construct system	Centaur System	BodyForm	SE?
Indications for Use:	degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies spondylolisthesis fracture spinal stenosis deformities (i.e., scoliosis, kyphosis, lordosis) tumors pseudarthrosis Failed Previous Fusion Surgery	SAME	SAME	YES
Components:	Plate, rod, nuts & cancellous bone screws	SAME	SAME	YES
Sterility:	No. Steam sterilize on-site before use.	SAME	SAME	YES
Profile:	<10mm	EQUIVALENT	EQUIVALENT	YES
Materials:	Titanium alloy	SAME	SAME	YES
Attachment:	Anterior - Thoraco/lumbar spine	SAME	SAME	YES
Manufacturer:	Aesculap, Inc.	Howmedica	Theken Surgical, LLC	YES
Surgical Approach:	Open, endoscopic or mini-surgical	Open or mini-surgical	Open or mini-surgical	NO - YES
Product Code:	KWQ	SAME	SAME	YES
K - Number:	Pending	K994347	K983622	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

AESCULAP, Inc.
Mr. David W. Schlerf
c/o Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K002824
Trade Name: **macs**^{TL} modular anterior construct system
Regulation Number: 21 CFR 888.3060
Regulatory Class: Class II
Product Code: KWQ
Dated: December 5, 2000
Received: March 13, 2001

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K002824

Device Name(s): **macs**^{TL} modular anterior construct system

Indications for Use:

KWQ 888.3060 – Spinal Intervertebral Body Fixation Orthosis

This anterolateral/anterior system consists of several vertebral screws, locking nuts, spine plates and rods. The points of attachment are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T1-L5). This system is intended to provide stabilization during the development of a solid spinal fusion.

When used as an anterolateral/anterior spine plate and rod system, the **macs**^{TL} modular anterior construct system is indicated for patients with:

- Degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spondylolysis
- Fracture
- Spinal stenosis
- Deformities (i.e., scoliosis, kyphosis, lordosis, whether neuromuscular or related to deficient posterior elements)
- Tumors (neoplastic disease)
- Pseudarthrosis
- Failed previous fusion surgery

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002824

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)